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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,935	11/01/2001	Robert Eric Montgomery	03136646	9955
7590	05/13/2004			
Timothy J Haller Niro Scavone Haller & Niro 181 West Madison Street Suite 4600 Chicago, IL 60602			EXAMINER JAGOE, DONNA A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/039,935	Applicant(s) MONTGOMERY, ROBERT ERIC	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/18/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1614

Claims 42-70 are pending in this application.

The Obviousness-Type Double Patenting rejections made in the paper mailed 9 September 2002 is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below. Applicant asserts that since application No. 10/050,196 claims priority from Provisional Application Serial No. 60/004,258, filed September 25, 1995, the double patenting rejection would be obviated. Applicant's attention is drawn to MPEP §804.02(iv), which states:

If multiple conflicting patents and/or pending applications are applied in double patenting rejections made in a single application, then prior to issuance of that application, it is necessary to disclaim each one of the conflicting double patenting references applied, rather than disclaiming only the conflicting double patenting reference with the earliest issue date (assuming at least one of the references is a patent). A terminal disclaimer fee is required for each terminal disclaimer filed. To avoid paying multiple terminal disclaimer fees, a single terminal disclaimer may be filed, wherein all the conflicting double patenting references are disclaimed therein.

Disclaiming each one of the conflicting double patenting references is **necessary** to avoid the problem of **dual ownership** of patents to patentably indistinct inventions in the event that the patent issuing from the application being examined **ceases to be commonly owned** with any one of the double patenting references that have issued or may issue as a patent. Note that 37 CFR 1.321(c)(3) requires that a terminal disclaimer "[i]nclude a provision that any patent granted on that application or any patent subject to the reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection."

The Statutory-Type Double Patenting rejection of claims 17-41 is no longer maintained in view of the amendment.

Rejection of claims 17-41 under 35 U.S.C. §112 1st paragraph is no longer maintained in view of the amendment.

The Examiner is in agreement with the persuasive remarks submitted concerning the outstanding 35 USC 102(a/e) and 35 U.S.C. 103(a) rejection made in the paper mailed 9 September 2002, in view of which the rejection is hereby withdrawn.

(New) Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 42-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,322,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to a single exit, dual compartment tube with a mixer comprising a first formulation of hydrogen peroxide precursor, a thickener, a carrier and a calcium chelating agent that is substantially free of an alkaline pH adjusting agent and a second formulation comprising an alkaline pH adjusting agent that is substantially free of a hydrogen peroxide precursor agent. The instant claims are drawn to a kit comprising a first tube and a second tube adapted to keep apart two formulations (a dual compartment tube with dual exit?). It differs in that the instant claims are drawn to a kit. It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the elements of the patent into a "kit". One would have been motivated to incorporate the elements of

Art Unit: 1614

the patent into a kit motivated by the standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use on a package.

2. Claims 42-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,536,628. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to a single exit, multi compartment vessel with a mixer whose compartments are adapted to keep them apart comprising a first formulation of hydrogen peroxide precursor, a thickener, a carrier that is substantially free of an alkaline pH adjusting agent and a second formulation comprising an alkaline pH adjusting agent that is substantially free of a hydrogen peroxide precursor agent wherein the mixture has a pH of greater than 5.5. The instant claims are drawn to a kit comprising a first tube and a second tube adapted to keep apart two formulations (a dual compartment tube with dual exit?). It differs in that the instant claims are drawn to a kit. It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the elements of the patent into a "kit". One would have been motivated to incorporate the elements of the patent into a kit motivated by the standard of practice in the pharmaceutical arts to enclose a composition in a vessel, and to enclose instructions for use on a package.

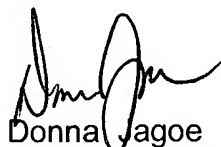
Art Unit: 1614

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 9:00 A.M. - 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Donna Jagoe
Patent Examiner
Art Unit 1614

4/21/04


MARIANNE C. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600